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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ENZO BIOCHEM, INC., et al.,	:	
Plaintiffs,	:	02-CV-8448 (RJS) 03-CV-3816 (RJS)
- against -	:	03-CV-3817 (RJS) 03-CV-3819 (RJS)
AMERSHAM PLC, et al.,	:	03-CV-8907 (RJS) 04-CV-1555 (RJS)
Defendants,	:	04-CV-4046 (RJS)
AND RELATED CASES NAMING	:	
MOLECULAR PROBES, INC., et al., PERKINELMER, INC., et al., ORCHID BIOSCIENCES, INC., et al., AFFYMETRIX, INC., ROCHE DIAGNOSTICS GMBH, et al., AS DEFENDANTS AND/OR DECLARATORY JUDGMENT PLAINTIFFS.	:	

ENZO'S STATEMENT OF MATERIAL FACTS
SHOWING GENUINE ISSUES TO BE TRIED IN OPPOSITION
TO DEFENDANTS' RENEWED JOINT MOTION FOR SUMMARY JUDGMENT

In accordance with Local Rule 56.1(b) of the United States District Court for the Southern District of New York, plaintiffs Enzo Biochem, Inc. and Enzo Life Sciences, Inc. (collectively, "Enzo") submit the following Statement of Material Facts in support of their Opposition to defendants' and declaratory-judgment plaintiffs' (collectively, "Defendants'") Joint Motion for Summary Judgment, thereby responding to each numbered paragraph in Defendants' Joint Statement Pursuant to Local Rule 56.1 ("Defendants' Rule 56.1 Statement"). As shown below, the material facts underlying Defendants' summary judgment motion are controverted, requiring trial on Enzo's claims.

Defendants' allegedly undisputed facts are reproduced below in block quotes followed by Enzo's response.[1]

I. DISPUTED FACTS RELATING TO DEFENDANTS' INFRINGEMENT OF ENZO'S PATENTS

A. The Ward Patents

1. Claim 1 of the '824 Patent, Claim 42 of the '767 Patent: Defendants' products with directly detectable labels satisfy the "A limitation"

DEFENDANTS' NO. 1

> Claim 1 of the '824 patent and claim 42 of the '767 patent require that "A . . . represents at least one component of a signaling moiety capable of producing a detectable signal."

ENZO'S NO. 1

Enzo does not dispute that the quoted language is present in the asserted patent claims, but otherwise disputes that this limitation is not infringed by the accused products for the reasons

[1] All exhibits referenced in Enzo's responses herein are attached to the Declaration of Justin MacLean in Support of Enzo's Opposition to Defendants' Joint Motion for Summary Judgment ("MacLean Decl.") unless otherwise noted.

set forth herein, in Enzo's opposition brief and in the expert Declaration of Dr. Richard Rankin Sinden ("Sinden Decl.").

DEFENDANTS' NO. 2

> The Court has ruled that A is "one component of a multi-component signaling moiety capable of indirect detection via an attached polypeptide." (Ex. 16, Claim Construction Order at 9-10, 23.)

ENZO'S NO. 2

Disputed. This is not a material fact, but a conclusion of law. Moreover, Enzo respectfully objects to the Court's claim construction as inconsistent with the instrinsic record and with Judge Arterton's construction of the same claim terms in the District of Connecticut (*see* Ex. 19), which was subsequently adopted by the Federal Circuit. *See Enzo Biochem Inc. v. Applera Corp.*, 599 F.3d 1325 (Fed. Cir. 2010). The Court's *Markman* order is self-explanatory.

DEFENDANTS' NO. 3

> The Court rejected Enzo's argument that the claimed A group "could…be the sole component of a signaling moiety and therefore operate alone as a directly detectable label." (Ex. 16, Claim Construction Order at 9.)

ENZO'S NO. 3

Disputed. This is not a material fact, but a conclusion of law. Moreover, Enzo respectfully objects to the Court's claim construction as inconsistent with the instrinsic record and with Judge Arterton's construction of the same claim terms in the District of Connecticut (*see* Ex. 19), which was subsequently adopted by the Federal Circuit. *See Enzo Biochem Inc. v. Applera Corp.*, 599 F.3d 1325 (Fed. Cir. 2010). The Court's *Markman* order is self-explanatory.

DEFENDANTS' NO. 4

> The accused products of Exhibit 23 all include, or result in, a directly detectable fluorescent group attached, through a chemical group, to a nucleotide or, in some instances, a polynucleotide. (Ex. 24, Burczak Decl. ¶¶11, 26, 30, 33, 34, 37, 38, 43, 45, 48, 50; Ex. 25, Mayer Decl. ¶¶20-21; Ex. 26, Singer Decl. ¶¶19-20.)

ENZO'S NO. 4

Disputed, except Enzo does not dispute that the signaling moieties in the accused products of Exhibit 23 to the Declaration of Robert J. Gunther, Jr. in Support of Defendants' Joint Motion for Summary Judgment ("Gunther Decl.") include two components, a fluorescent group and a chemical group. The accused products in Gunther Decl. Ex. 23 are all capable of being detected directly or indirectly. (*See* Amersham specification sheets (Ex. 32); Burczak Tr. 100:3-101:15, Mar. 29, 2007 (Ex.31); PerkinElmer specification sheets (Ex. 33); Mayer Tr. 140:9-143:3, Mar. 17, 2003 (Ex. 24); Mayer Tr. 113:7-21, Apr. 12, 2007 (Ex. 75).)

Each and every accused product identified on Gunther Decl. Ex. 23 satisfies the requirement "that 'A' be one component of a multi-component signaling moiety capable of indirect detection via an attached polypeptide," because each dye on these products is capable of binding with a labeled antibody (a polypeptide) that can then be detected. (Sinden Decl. ¶¶ 52-53, 72; Exs. 12A-E to Sinden Decl.; Burczak Tr. 100:3-101:15, Mar. 29, 2007 (Ex. 31); Mayer Tr. 140:9-143:3, Mar. 17, 2003 (Ex. 24).) Both Amersham and PerkinElmer sell labeled antibodies that bind to fluorescein. (*See* Amersham specification sheets (Ex. 32); Burczak Tr. 100:3-101:15, Mar. 29, 2007 (Ex. 31); PerkinElmer specification sheets (Ex. 33); Mayer Tr. 140:9-143:3, Mar. 17, 2003 (Ex. 24); Sinden Decl. ¶ 54.) In these labeled antibody products, it is the label on the antibody that is detected. (Sinden Decl. ¶ 54; Mayer Tr. 140:9-143:3, Mar. 17, 2003 (Ex. 24).)

Fluorescein can be one component of a multi-component signaling moiety capable of indirect detection via an attached polypeptide. (Sinden Decl. ¶ 54; Exs. 12A-E to Sinden Decl.; Burczak Tr. 100:3-101:15, Mar. 29, 2007 (Ex. 31); Mayer Tr. 140:9-143:3, Mar. 17, 2003 (Ex. 24); PerkinElmer specification sheets (Ex. 33); Amersham specification sheets (Ex. 32).) Labeled antibody products can be attached to fluorescein for detection. (Sinden Decl. ¶¶ 53-54;

Exs. 12A-E to Sinden Decl.; Burczak Tr. 100:3-101:15, Mar. 29, 2007 (Ex. 31); Mayer Tr. 140:9-143:3, Mar. 17, 2003 (Ex. 24); PerkinElmer specification sheets (Ex. 33); Amersham specification sheets (Ex. 32).) PerkinElmer sells such products namely Anti-Fluorescein AP Conjugate, fluorescein with an attached antibody which is used to amplify the detection signal. (Sinden Decl. ¶ 54; Exs. 12B, 12D to Sinden Decl.; Mayer Tr. 140:9-143:3, Mar. 17, 2003 (Ex. 24); PerkinElmer specification sheets (Ex. 33).) Thus, PerkinElmer accused products are capable of indirect detection via an attached polypeptide. (Sinden Decl. ¶¶ 53-54, 72; Exs. 12B, 12D to Sinden Decl.; Mayer Tr. 140:9-143:3, Mar. 17, 2003 (Ex. 24); PerkinElmer specification sheets (Ex. 33).)

During her deposition on March 17, 2003, Patricia Mayer explained that in PerkinElmer's TSA Amplication system, REDACTED

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REDACTED Thus, in the TSA system fluorescein is one component of a multi-component signaling moiety capable of indirect detection via an attached polypeptide. (*Id.*)

Patricia Mayer's remarks were amplified at her subsequent deposition on April 12, 2007, where she explained that REDACTED

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REDACTED It is indisputable that Defendants' directly detectable products are all "capable of indirect detection via an attached polypeptide." (*Id.*; Sinden Decl. ¶¶ 52-53, 72; Exs. 12A-E to Sinden Decl.)

With respect to Amersham's Gene Images Random-Prime Labelling and Detection System, Dr. Burczak testified that REDACTED

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At the summary judgment oral argument before Judge Sprizzo, Defendants' counsel echoed the admission that fluorescent dyes are capable of indirect detection via an antibody:

> COUNSEL FOR DEFENDANTS: "We agree that fluorescent dyes in theory could be detected in that manner.... [T]his issue of, can a fluorescent dye be capable of being detected through an antibody. We agree fluorescent dyes can be detected in that way."

(Ex. 78, Hearing Tr. 183:9-10 and 189:2-5, July 17, 2007).

As the claim charts attached as Exhibits 12A-E of Dr. Sinden's declaration demonstrate, the accused products listed on Gunther Decl. Ex. 23 infringe Claim 1 of the '824 Patent and Claim 42 of the '767 Patent by meeting each and every limitation of the asserted claims. (Sinden Decl. ¶¶ 52-53, 72; Ex. 12 to Sinden Decl.)

DEFENDANTS' NO. 5

> For each accused product of Exhibit 23, the fluorescent label operates alone and without the addition of other chemical groups to produce a directly detectable signal and thus is not "one component of a multi-component signaling moiety." (Ex. 24, Burczak Decl. ¶¶33, 37, 45, 50, 55; Ex. 25, Mayer Decl. ¶21; Ex. 26 Singer Decl. ¶21.)

ENZO'S NO. 5

Disputed. The accused products in Gunther Decl. Ex. 23 are all capable of being detected directly or indirectly. *See* Enzo's No. 4. The label of the accused products in Gunther Decl. Ex. 23 are also "one component of a multi-component signaling moiety." For instance, REDACTED

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REDACTED Similarly, Amerham's Cy Dye-labelled NTP products and FluorX products, for example, include a fluorescent "dye group" component that is covalently attached to another "amine linker" component which, in turn, covalently attaches to the "nucleotide base" upon incorporation into a DNA/RNA strand. (Gunther Decl. Ex. 24, Burczak Decl. ¶¶ 30-55.) These multi-component moieties can be seen quite clearly in the figures of Defendants' declarations wherein the "amine linker" component is circled and the fluorescent dye component is shown attached to and extending towards the upper right:

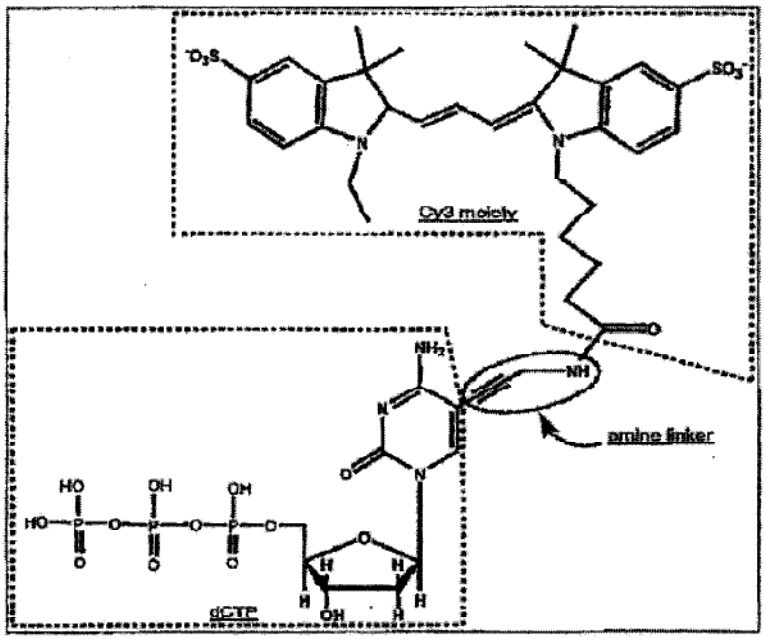


FIGURE 1

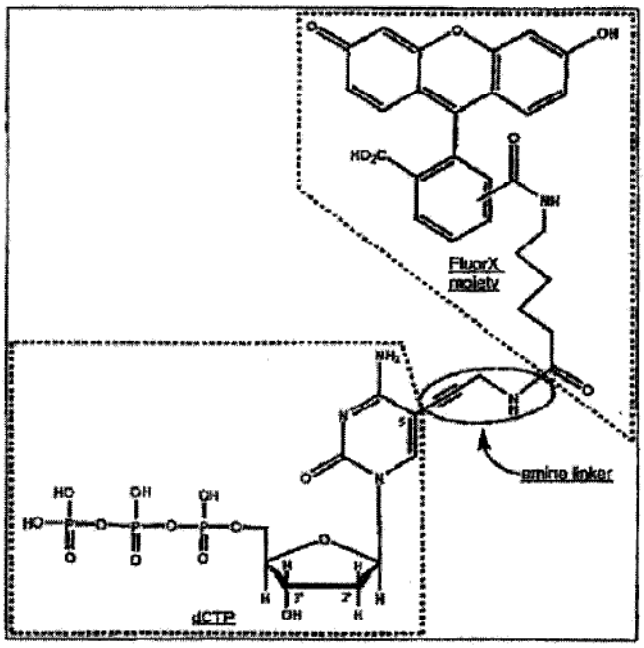
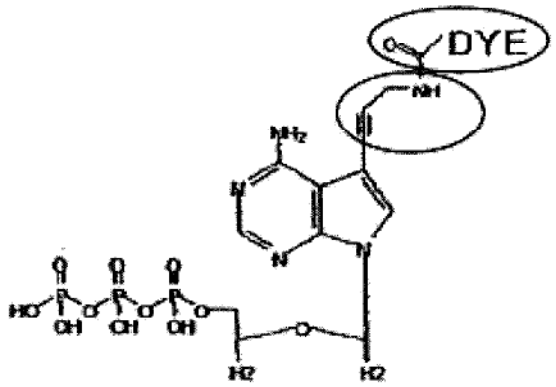


FIGURE 2

(*Id.* Figs. 1 & 2). Likewise, PerkinElmer's products, including its Acyclonucleotides and dideoxynucleotides, also include a multi-component labeling moiety that comprises a fluorescent dye component and a linker component as shown, for example, below:



As the claim charts attached as Exhibit 12A-E of Dr. Sinden's declaration demonstrate, the accused products listed on Gunther Decl. Ex. 23 infringe Claim 1 of the '824 Patent and

Claim 42 of the '767 Patent by meeting each and every limitation of the asserted claims. (Sinden Decl. ¶¶ 52-53, 72; Exs. 12A-E to Sinden Decl.)

DEFENDANTS' NO. 6

> The accused products of Exhibit 23 are not designed to be detected indirectly "via an attached polypeptide." (Ex. 24, Burczak Decl. ¶¶33, 37, 45, 50, 55; Ex. 25, Mayer Decl. ¶21; Ex. 26, Singer Decl. ¶21.)

ENZO'S NO. 6

Disputed. The accused products in Gunther Decl. Ex. 23 are all capable of being detected directly or indirectly. *See* Enzo's No. 4.

DEFENDANTS' NO. 7

> The function of the fluorescent labels of the accused products of Exhibit 23 is to provide a directly detectable signal. (Ex. 27, Blackburn SJ Decl. ¶¶143-145.)

ENZO'S NO. 7

Disputed. The function of the fluorescent labels of the accused products in Gunther Decl. Ex. 23 is to label and enable detection of a nucleic acid sequence in a way that does not substantially interfere with hybridization with its complementary nucleic acid sequence and/or detection. (Sinden Decl. ¶ 57.) The labels need only be capable of indirect detection. (Ex. 20, *Markman* Order at 23). As indicated above in Enzo's No. 4, the accused products of Gunther Decl. Ex. 23 are all capable of indirect detection via an attached polypeptide. (*See* Enzo's No. 4.)

Furthermore, Defendants offer products that utilize labeled anti-fluorescein antibodies. (Sinden Decl. ¶ 54; Exs. 12A-E to Sinden Decl.; Burczak Tr. 100:3-101:15, Mar. 29, 2007 (Ex. 31); Mayer Tr. 140:9-143:3, Mar. 17, 2003 (Ex. 24).) Labeled antibodies are made against fluorescein creating anti-fluorescein; the labeled antibodies are then detected. (Sinden Decl. ¶ 54;

Exs. 12A-E to Sinden Decl.; Burczak Tr. 100:3-101:15, Mar. 29, 2007 (Ex. 31); Mayer Tr. 140:9-143:3, Mar. 17, 2003 (Ex. 24).)

DEFENDANTS' NO. 8

> The function of the claimed A group is to form a stable complex with a detectable polypeptide. (*See* Ex. 27, Blackburn SJ Decl. ¶¶143-145.)

ENZO'S NO. 8

Disputed. The function of the claimed A group is to label and enable detection of a nucleic acid sequence in a way that does not substantially interfere with hybridization with its complementary nucleic acid sequence and/or detection. (Sinden Decl. ¶ 57.)

DEFENDANTS' NO. 9

> To provide a directly detectable signal, the fluorescent labels of the accused products of Exhibit 1 [sic] absorb excitation light at one wavelength and emit fluorescent light at another. (Ex. 27, Blackburn SJ Decl. ¶¶143-145.)

ENZO'S NO. 9

Disputed. The function of the fluorescent labels of the accused products in Gunther Decl. Ex. 23 (assuming this is what is really meant by "Exhibit 1" in Defendants' No. 9) is not limited to providing a directly detectable signal. Rather, the function of the fluorescent labels of the accused products in Gunther Decl. Ex. 23 is to label and enable detection of a nucleic acid sequence in a way that does not substantially interfere with hybridization with its complementary nucleic acid sequence and/or detection. (Sinden Decl. ¶ 57.) *See* Enzo's No. 7. In order to perform this function, the fluorescent labels of the accused products in Gunther Decl. Ex. 23 attach the detectable multi-component signaling moiety to a specific site on the nucleic acid base. (Sinden Decl. ¶ 57.) The fluorescent labels of the accused products in Gunther Decl. Ex.

23 absorb excitation light at one wavelength and emit a soluble signal in the form of fluorescent light at another.

DEFENDANTS' NO. 10

> To achieve its function, the claimed A group engages in a binding interaction with a polypeptide. (Ex. 27, Blackburn SJ Decl. ¶¶143-145.)

ENZO'S NO. 10

Disputed. As construed by the Court, the claimed A group need only be capable of indirect detection via an attached polypeptide. *See* Ex. 20, *Markman* order, at 9. There is no requirement that it actually do so. *Id.* Rather, the claimed A group achieves its function of labeling and enabling detection of a nucleic acid sequence in a way that does not substantially interfere with hybridization with its complementary nucleic acid sequence and/or detection (*see* Enzo's No. 8) by attaching the detectable multi-component label to a specific site on the nucleic acid base. (Sinden Decl. ¶ 57.)

DEFENDANTS' NO. 11

> Enzo may allege for at least certain defendants that a small three-carbon group, which is part of a spacer between the fluorescent label and the nucleotide base, constitutes the claimed A group. The three-carbon group that Enzo now identifies as the claimed A group is not even hypothetically capable of indirect detection via an attached polypeptide. (Ex. 27, Blackburn SJ Decl. ¶151-153.)

ENZO'S NO. 11

Disputed. Enzo does not assert that the linker groups of the accused products constitute the "A" limitation of Claim 1 of the '824 Patent and Claim 42 of the '767 Patent, but that those linker groups referred to Defendants are one component of a multi-component signaling moiety

and the fluorescent molecule is the other component. (Sinden Decl. ¶¶ 52-53, 72; Exs. 12A-E to Sinden Decl.)

DEFENDANTS' NO. 12

> The function of the three-carbon group within the accused products of Exhibit 23 is to serve as part of the spacer that provides distance between the fluorescent dye and the nucleotide. (Ex. 27, Blackburn SJ Decl. ¶¶154-55.)

ENZO'S NO. 12

Disputed. *See* Enzo's No. 11.

The function of this component part is irrelevant to the disputed claim terms on this motion.

DEFENDANTS' NO. 13

> The three-carbon group of the accused products of Exhibit 23 achieves this function by providing a chemical linkage between the fluorescent dye and the nucleotide. (Ex. 27, Blackburn SJ Decl. ¶¶154-55.)

ENZO'S NO. 13

Disputed. *See* Enzo's No. 11.

The function of this component part is irrelevant to the disputed claim terms on this motion.

DEFENDANTS' NO. 14

> The three-carbon group of the accused products of Exhibit 23 results in increased distance between the fluorescent dye and the nucleotide. (Ex. 27, Blackburn SJ Decl. ¶¶154-55.)

ENZO'S NO. 14

Disputed. *See* Enzo's No. 11.

The function of this component part is irrelevant to the disputed claim terms on this motion.

2. The Acyclonucleotide Products Satisfy Claim 42 Of The '767 Patent Under The Doctrine of Equivalents

DEFENDANTS' NO. 15

Claim 42 of the '767 patent requires a "nucleotide" that includes a pentose sugar. (Ex. 16, Claim Construction Order at 6-8).

ENZO'S NO. 15

Disputed. This is not a material fact, but a conclusion of law. Enzo respectfully objects to the Court's claim construction of this term in the preamble and notes that Defendants have not shown that it is an affirmative limitation of the claim. The Court's *Markman* order is self-explanatory.

DEFENDANTS' NO. 16

The accused AcycloPrime products of Exhibit 28 lack a pentose sugar. (Mayer Decl ¶17.)

ENZO'S NO. 16

Disputed. Per Defendants' own product literature, the Acyclonucleotide products are incorporated into and form an integral part of an "oligonucleotide" sequence, which includes both multiple nucleotides and pentose sugars. (*See, e.g.*, Gunther Decl. Ex. 25, Mayer Decl., Ex. 1 at PE053621, Section IV "…incorporation of a Fluorescent Acyclo Terminator into a primer oligonucleotide…."; Sinden Decl. ¶ 63.) Accordingly, the acyclonucleotide products are undeniably "comprised of" (i.e., include, but not limited to) both nucleotides and pentose sugars on incorporation into an oligonucleotide sequence as intended.

DEFENDANTS' NO. 17

During prosecution of application U.S.S.N. 255,223 (the original Ward application which led to the '767 patent), Enzo rebutted a § 103 obviousness rejection by arguing "[t]hat the references (Bergstrom and Ruth) are only directed to pyrimidine nucleosides" (which differ from nucleotides in that they lack a phosphate group) and there "is absolutely

> no teaching or suggestion in any of these references of nucleotides or chemically labeled nucleotides, either pyrimidine nucleotides or purine nucleotides." (Ex. 29, Supp. Comm. filed 9/21/82 p. 3.)

ENZO'S NO. 17

Disputed. Defendants misquote Enzo's statement appearing on page 3 of September 21, 1982 Supplemental Communication. (*See* Supp. Comm., U.S. Patent Application No. 255,223, at 3, (dated Sept. 21, 1982) (Ex. 37).) The statement should read, "the references cited by the Examiner are concerned with pyrimidine nucleosides." Defendants only provide excerpts of this Supplemental Communication. (Ex. 37.) The language of the Supplemental Communication is self-explanatory and distinguishes the references on numerous bases non of which, separately or together, create an estoppel as to the accused acyclonucleotide products. Indeed, the Supplemental Communication offers no statement related to pentose sugars, or whether acyclosugars are excluded from the scope of the claim, and thus do not estop a finding of equivalency for each of the products in Gunther Decl. Ex. 28. (*Id.*)

DEFENDANTS' NO. 18

> During prosecution of application U.S.S.N. 255,223 (the original Ward application which led to the '767 patent), Enzo represented that "[i]t is not seen how one skilled in the art having the disclosures of these references in view would come away with any teaching or suggestion of applicants' claimed invention which is nucleotide-based." (Ex. 29, Supp. Comm. filed 9/21/82 p. 3.)

ENZO'S NO. 18

Disputed. Defendants only provide excerpts of this Supplemental Communication. (*See* Supp. Comm., U.S. Patent Application No. 255,223, at 3, (dated Sept. 21, 1982) (Ex. 37).) The language of the Supplemental Communication is self-explanatory and distinguishes the references on numerous bases non of which, separately or together, create an estoppel as to the accused acyclonucleotide products. Indeed, the Supplemental Communication offers no

statement related to pentose sugars, or whether acyclosugars are excluded from the scope of the claim, and thus do not estop a finding of equivalency for each of the products in Gunther Decl. Ex. 28. (*Id.*)

DEFENDANTS' NO. 19

> In parent application, U.S.S.N. 496,915, which matured into the '955 patent, Enzo distinguished the claimed subject matter over prior art references on the basis that the references "do not refer to or suggest applicants' nucleotides because they only refer to bases without sugars." (Ex. 30, Amdmt filed 6/25/85 at 26.)

ENZO'S NO. 19

Disputed. Defendants only provide excerpts of this Amendment. (*See* Amendment, U.S. Patent Application No. 496,915, at 26, (dated June 25, 1985) (Ex. 38).) The language of the Amendment is self-explanatory and distinguishes the references on numerous bases non of which, separately or together, create an estoppel as to the accused acyclonucleotide products. Indeed, the Supplemental Communication offers no statement related to pentose sugars, or whether acyclosugars are excluded from the scope of the claim, and thus do not estop a finding of equivalency for each of the products in Gunther Decl. Ex. 28. (*Id.*)

3. The dideoxynucleotides infringe Claim 1 of the '824 Patent

DEFENDANTS' NO. 20

> The claimed method of claim 1 of the '824 patent requires use of a compound with the depicted nucleic acid polymer structure. (Ex. 8, '824 patent col. 30:55-31:10.)

ENZO'S NO. 20

Disputed. This is not a statement of fact, but a conclusion of law as to claim scope. Defendants never raised this issue during *Markman*, and Defendants' proposed construction is untimely and incorrect. The accused products in Gunther Decl. Ex. 34 literally infringe '824 claim 1. *See* Enzo's No. 21.

DEFENDANTS' NO. 21

> The claimed structure requires a phosphate group attached to the 3' position of the labeled nucleotide. (Ex. 27, Blackburn SJ Decl. ¶156.)

ENZO'S NO. 21

Disputed. Defendants did not request -- and the Court did not construe -- whether Claim 1 of the '824 requires a phosphate group attached to the 3' position of the depicted polymer structure. (Ex. 20, *Markman* order, at 1-24.) The claimed structure, as interpreted by one of skill in the art, does not require a phosphate group attached to the 3' position of the labeled nucleotide. (Sinden Decl. ¶ 67.) '824 claim 1 depicts a polynucleotide with brackets around the 3' phosphate group. (*Id.*) The claim says p can be 0, which means that the nucleotide labeled with A would, by the requirement of having been incorporated, not include a phosphate, it would possess a 3'OH or 3'H if a deoxy- or dideoxynucleotide were incorporated, respectively. (*Id.*) One of ordinary skill in the art would immediately recognize that this claim clearly only requires "a phosphate group attached to the 3' position of the labeled nucleotide" when p ≥1. (*Id.*) Thus, Amersham and PerkinElmer's construction of claim 1 is scientifically incorrect. (*Id.*)

The process of DNA synthesis involves the addition of a mononucleotide to the 3' OH terminus of a nascent, growing chain. (Sinden Decl. ¶ 68.). The form of the nucleotide required for enzymatic incorporation by DNA (or RNA) polymerase is a triphosphate. (*Id.*) The ∀-phosphate bonds through the 3' OH of the terminal base, forming the phosphodiester bond, while the ∃-(phosphates are hydrolyzed to energetically drive the reaction. (*Id.*) Most importantly, the incoming nucleotide donates the phosphate. In the case of a dideoxynucleotide, nucleotide or acyclonucleotide, the chain is terminated and there can be no PO_4 attached to the 3' end of the chain. (*Id.*)

Further, the claim language itself expressly discloses a situation for dideoxynucleotides. (Sinden Decl. ¶ 69.) The claim states that *p* can be zero (0). (*Id.*) When $p = 0$ there can be no phosphodiester bond linking the 5'-carbon of the *p* nucleotide to the 3'-carbon of the *n* nucleotide. This is because *n* is the terminal nucleotide of the polynucleotide chain. (*Id.*) The chemical group attached to a 3'-carbon will clearly depend on the method by which that particular polynucleotide was synthesized. (*Id.*) For terminator-based DNA sequencing, DNA polymerase catalyzes the addition of dye-labeled dideoxyribonucleotides (the n^{th} nucleotide) to the nascent chain. (*Id.*) This results in an oligonucleotide having a 3' H at the 3' end of the DNA (on the 3' carbon of the sugar). (*Id.*) One skilled in the art would understand that the specification and claim language describes a situation where the phosphate need not be present, when $m = >1$, $n = 1$ and $p = 0$. (*Id.*)

DEFENDANTS' NO. 22

> The accused products of Exhibit 34 do not have a 3' phosphate group because they are dideoxynucleotide monomers, which have a hydrogen atom at the 3' position. (Ex. 27, Blackburn SJ Decl. ¶157; Ex. 24, Burczak Decl. ¶24; Ex. 25, Mayer Decl. ¶25.)

ENZO'S NO. 22

Disputed and immaterial, because the accused products in Gunther Decl. Ex. 34 infringe '824 claim 1. *See* Enzo's No. 21.

DEFENDANTS' NO. 23

> When a dideoxynucleotide monomer is used to make a DNA polymer, the 3' hydrogen prevents another nucleotide, or any other chemical group, from being attached to the 3' polymer end. (Ex. 24, Burczak Decl. ¶24; Ex. 25, Mayer Decl. ¶26.)

ENZO'S NO. 23

Disputed to the extent this statement is used as a basis for noninfringement, because the accused products in Gunther Decl. Ex. 34 infringe '824 claim 1. *See* Enzo's No. 21.

DEFENDANTS' NO. 24

> Because they terminate DNA polymer growth, the accused labeled dideoxynucleotide monomers of Exhibit 34 are always the final nucleotide at that end. (Ex. 24, Burczak Decl., ¶24; Ex. 25, Mayer Decl., ¶25, 26.)

ENZO'S NO. 24

Disputed to the extent this statement is used as a basis for noninfringement, because the accused products in Gunther Decl. Ex. 34 infringe '824 claim 1. *See* Enzo's No. 21.

DEFENDANTS' NO. 25

> It is impossible for the products of Exhibit 34 to result in the structure with a phosphate group attached at the 3' position as required by the claim. (Ex. 27, Blackburn SJ Decl. ¶158.)

ENZO'S NO. 25

Disputed that a phosphate group attached at the 3' position is required by the claim. The accused products in Gunther Decl. Ex. 34 infringe '824 claim 1. *See* Enzo's No. 21.

DEFENDANTS' NO. 26

> The 3' hydrogen atom of the accused products of Exhibit 34 prevents further extension of a DNA polymer making the products useful for the Sanger dideoxy sequencing method, whereas the 3' phosphate group required by the claim allows for further polymer extension and cannot be used for such sequencing method. (Ex. 27, Blackburn SJ Decl. ¶¶158-59.)

ENZO'S NO. 26

Disputed that a phosphate group attached at the 3' position is required by the claim. The accused products in Gunther Decl. Ex. 34 infringe '824 claim 1. *See* Enzo's No. 21.

B. THE '373 PATENT

1. Defendants Meet The Probe Limitation

DEFENDANTS' NO. 34

> Claim 1 of United States Patent No. 4,994,373 (the "373 patent") recites "a method for detecting a polynucleotide sequence" that requires "fixing

> said polynucleotide sequence to a solid support" and "forming an entity comprising said polynucleotide sequence hybridized to a polynucleotide or oligonucleotide probe, said probe having attached thereto a chemical label." (Ex. 10, '373 patent col. 13:31-46; *see also* Ex. 16, Claim Construction Order at 20.)

ENZO'S NO. 34

Undisputed that the excerpted language is correctly quoted.

DEFENDANTS' NO. 35

> The '373 patent defines an "analyte" as "[a] substance…whose presence is to be detected and, if desired, quantitated." (Ex. 10, '373 patent col. 1:27-34; *see also* Ex. 16, Claim Construction Order at 20.)

ENZO'S NO. 35

Undisputed that the excerpted language is correctly quoted but otherwise disputed in that this statement is not a material fact, but a conclusion of law.

DEFENDANTS' NO. 36

> The '373 patent defines "probe" as a "labeled polynucleotide or oligonucleotide sequence which is complementary to a polynucleotide or oligonucleotide of a particular analyte and which hybridizes to said analyte sequence." (Ex. 10, '373 patent col. 1:42-45; *see also* Ex. 16, Claim Construction Order at 19-20.)

ENZO'S NO. 36

Disputed. The actual text of the '373 patent specification reads: "labeled polynucleotide or oligonucleotide sequence which is complementary to a polynucleotide or oligonucleotide sequence of a particular analyte and which hybridizes to said analyte sequence." ('373 patent col. 1, ll. 42-45, emphasis added). Further disputed in that this statement is not a material fact, but a conclusion of law.

DEFENDANTS' NO. 37

> Claim 1 of the '373 patent - and all of the remaining asserted claims, which all depend from claim 1 - require a test format whereby "the sample, which is the substance within which one is looking for the analyte, must be fixed to the solid support, and the probe, which is a labeled

> sequence complementary to the analyte, cannot be so fixed." (Ex. 16, Claim Construction Order at 20, 24, 18 n.21.)

ENZO'S NO. 37

Undisputed that the excerpted language is correctly quoted but otherwise disputed in that this statement is not a material fact, but a conclusion of law. In any event, neither claim 1 of the '373 patent nor the *Markman* Order articulates a "test format" at any point. ('373 patent, *Markman* Order).

DEFENDANTS' NO. 38

> Claim 1 of the '373 patent - and all of the remaining asserted claims, which all depend from claim 1 - "require[] that the probe be labeled." (Ex. 16, Claim Construction Order at 20, 18 n.21.)

ENZO'S NO. 38

Undisputed that the excerpted language is correctly quoted but otherwise disputed in that this statement is not a material fact, but a conclusion of law. Enzo further disputes any implication of Defendants' No. 38 that either a labeled analyte or an unlabeled probe would not infringe under the doctrine of equivalents. In fact, the accused products in Gunther Decl. Ex. 35 do infringe the '373 patent under the doctrine of equivalents, as the differences between the accused products and the disputed limitation of the claimed invention are insubstantial. (Declaration of Archibald S. Perkins ("Perkins Decl.") ¶¶ 14, 48-51.) *See* Enzo's No. 79-92.

DEFENDANTS' NO. 39

> The accused products of Exhibit 35 do not include or result in a sample fixed to a solid support. (Ex. 36, McGall Decl. ¶4; Ex. 32, Will Decl. ¶3; Ex. 25 [sic], Burczak Decl., ¶20, 21, 39, 44, 47, 49; Ex. 25, Mayer Decl. ¶10.)

ENZO'S NO. 39

Plaintiffs dispute Defendants' reliance on Burczak Decl. ¶¶ 39 and 47 to support the statement of Defendants' Paragraph 39. Burczak Decl. ¶¶ 39 and 47 do not address the issue of fixing to a solid support. (Burczak Decl. ¶¶ 39, 47).

Also disputed to the extent that the accused products of Gunther Decl. Exhibit 35 affix a nucleic acid sequence to a solid support and infringe the asserted claims of the '373 patent under the doctrine of equivalents by meeting each and every limitation literally or equivalently. (Declaration of Archibald S. Perkins ("Perkins Decl.") ¶¶ 14, 48-51.) *See* Enzo's No. 79-92.

DEFENDANTS' NO. 40

> In each of the accused products of Exhibit 35, the probe (and not the sample) is fixed (Ex. 36, McGall Decl. ¶¶4, 6; Ex. 32, Will Decl. ¶3; Ex. 24, Burczak Decl., ¶21, 32, 44,49; Ex. 35, Mayer Decl., ¶ 30)

ENZO'S NO. 40

Disputed to the extent that in each of the accused products of Gunther Decl. Ex. 35 a nucleic acid sequence is affixed, and there is infringement of the asserted claims of the '373 patent under the doctrine of equivalents by meeting each and every limitation literally or equivalently. (Declaration of Archibald S. Perkins ("Perkins Decl.") ¶¶ 14, 48-51.) *See* Enzo's No. 79-92.

DEFENDANTS' NO. 41

> The accused products of Exhibit 35 do not include or result in a labeled probe. (Ex. 36, McGall Decl. ¶¶4, 7; Ex. 32, Will Decl. ¶3; Ex. 24, Burczak Decl., ¶121 [sic], 32, 44, 49; Ex. 25, Mayer Decl. ¶ 31)

ENZO'S NO. 41

Disputed to the extent that the accused products of Gunther Decl. Ex. 35 include or result in a labeled nucleic acid sequence that is unfixed and infringe the asserted claims of the '373 patent under the doctrine of equivalents by meeting each and every limitation literally or

equivalently. (Declaration of Archibald S. Perkins ("Perkins Decl.") ¶¶ 14, 48-51.) *See* Enzo's No. 79-92.

DEFENDANTS' NO. 42

> Because the '373 patent requires that the probe be labeled, it would be impossible to conduct tests with the probe fixed to the solid support, since to do so would result in false positives. (Ex. 16, Claim Construction Order at 20, *citing* hearing testimony of Dr. George Stark; *see also* Ex. 36, McGall Decl. ¶10)

ENZO'S NO. 42

Undisputed that a person of skill in the art would understand that if tests were conducted with a labeled nucleotide fixed to a solid support, they would result in false positives and thus would know to label whichever of the two complementary sequences is not fixed. Disputed to the extent that the implication of Defendants' No. 42 that no unlabeled probe can infringe under the doctrine of equivalents, or that no probe fixed to a solid support can infringe under the doctrine of equivalents. In fact, the accused products in Gunther Decl. Ex. 35 do infringe the '373 patent under the doctrine of equivalents, as the differences between the accused products and the claimed invention are insubstantial. (Declaration of Archibald S. Perkins ("Perkins Decl.") ¶¶ 14, 48-51.) *See* Enzo's No. 79-92.

DEFENDANTS' NO. 43

> The configuration of the accused array products of Exhibit 35 - unlabeled probe attached to solid support, and labeled analyte free-floating before hybridization - enhances mass production and enables complicated experiments that would not be possible using the format claimed in the '373 patent. (Ex. 36, McGall Decl. ¶¶9, 11)

ENZO'S NO. 43

Disputed that the above statement applies to the accused products in Gunther Decl. Ex. 35. The McGall Declaration relates only to accused Affymetrix products, thus, Defendants' No.

43 as applied to accused Amersham, PerkinElmer and Roche products is not supported by admissible evidence.

Disputed that the '373 requires a "test format" of any sort. *See* Enzo's No. 37.

Disputed to the extent that Defendants imply that the enhancement of mass production and the enablement of complicated experiments are relevant to the function/way/result test of the doctrine of equivalents or whether Defendants' accused products infringe. The accused products of Gunther Decl. Ex. 35 infringe the asserted claims of the '373 patent under the doctrine of equivalents by meeting each and every limitation literally or equivalently. (Declaration of Archibald S. Perkins ("Perkins Decl.") ¶¶ 14, 48-51.) *See* Enzo's No. 79-92. This is so even if the accused products are more efficient or perform additional functions. *See Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1482 (Fed. Cir. 1984).

2. Defendants Meet The Soluble Signal Limitation

DEFENDANTS' NO. 44

> Claim 1 of the '373 patent - and all of the remaining asserted claims, which all depend from claim 1 - require generation of a "soluble signal." (Ex. 10, '373 patent col. 13:44-46 (Ex. 20); *see also* Ex. 16, Claim Construction Order at 20-21, 18 n.21.)

ENZO'S NO. 44

Disputed. This is not a material fact, but an attempt to state a conclusion of law.

DEFENDANTS' NO. 45

> Claim 1 of the '373 patent - and all of the remaining asserted claims, which all depend from claim 1 - require in their use of "soluble signal," the creation of a soluble, or uniformly dispersed, product which generates a detectable signal. (Ex. 16, Claim Construction Order at 24, 18 n.21.)

ENZO'S NO. 45

Disputed. This is not a material fact, but a conclusion of law. Moreover, Enzo respectfully objects to the Court's claim construction. The Court's *Markman* order is self-

explanatory and conflicts with Judge Arterton's construction in the District of Connecticut. (Ex. 19.) In any event, this statement is immaterial, because the accused products of Gunther Decl. Ex. 35 meet the "soluble signal" limitation as construed. *See* Enzo's No. 46, 102-106.

DEFENDANTS' NO. 46

> The accused products of Exhibit 35 do not use or result in a "soluble signal" - *i.e.*, they do not create a soluble, or uniformly dispersed, product which generates a detectable signal. (Ex. 36, McGall Decl. ¶¶13-14; Ex. 32, Will Decl. ¶¶4-5; Ex. 24, Burczak Decl., ¶31, 43, 48; Ex. 25, Mayer Decl. ¶¶33; *see also* Ex. 16, Claim Construction Order at 24, 20-22; Ex. 37, Perkins Decl. ¶31.)

ENZO'S NO. 46

Disputed. The accused products of Gunther Decl. Ex. 35 use or result in a "soluble signal." In the method of detection of claim 1, as described in the '373 patent and as practiced by Defendants' accused products, an instrument designed for quantitation, such as a spectrophotometer, emits light onto the hybridization reaction ("incident light"). (Perkins Decl. ¶ 29; '373 patent, col. 7, ll. 31-36). The signal-generating moiety is a fluorescent molecule attached to the hybridized polynucleotide sequences. (Perkins Decl. ¶ 29.) The incident light interacts with the fluorescent molecule, and through this interaction the incident light is altered in some way; for instance the fluorescent molecule absorbs the energy of the incident light resulting in the excitation of an electron of the fluorescent molecule and the emission of a new wavelength of light (*i.e.*, generating fluorescence). (*Id.*) The light generated is a detectable signal that is uniformly dispersed into solution and may be measured by a spectrophotometer or other suitable instrument. (*Id.*) Defendants' expert, Dr. Blackburn, has acknowledged that the light emitted from a fluorescent molecule is emitted in all directions. (Ex. 80, Markman Tr. 738:1-739:4.) This soluble signal never precipitates. (Perkins Decl. ¶ 29.)

DEFENDANTS' NO. 47

> The accused products of Exhibit 35 utilize a tethered fluorescent molecule that is not dissolved or in a solution. (Ex. 36, McGall Decl., ¶¶13-14; Ex. 32, Will Decl., ¶¶4-5; Ex. 24, Burczak Decl., ¶31, 43, 48; Ex. 25, Mayer Decl., ¶33; *see also* Ex. 16, Claim Construction Order at 22; Ex. 37, Perkins Decl. ¶27.)

ENZO'S NO. 47

Disputed to the extent that Defendants insinuate that the accused products of Gunther Decl. Ex. 35 do not infringe based on use of what they refer to as a "tethered fluorescent molecule." The specification and claims of the '373 patent explicitly call for "tethering" or covalent/direct attachment of fluorescent chemical labels capable of generating the claimed soluble signal. ('373 patent, claims 18, 19, and 27.; Perkins Decl. ¶ 31.)

DEFENDANTS' NO. 48

> The non-soluble signals utilized by the accused products of Exhibit 35 allow users of those products to pinpoint the location of a hybridized sequence, whereas the soluble signal of '373 claim 1 does not, because it is uniformly dispersed. (Ex. 36, McGall Decl. ¶14; Ex. 32, Will Decl. ¶5; Ex. 24, Burczak Decl., ¶31, 43, 48; Ex. 16, Claim Construction Order at 24, 20-22; Ex. 37, Perkins Decl. ¶27.)

ENZO'S NO. 48

Disputed that signals are "non-soluble" in the context of the '373 claim. The accused products of Gunther Decl. Ex. 35 meet the claimed limitation. *See* Enzo's No. 46, 102-106.

Enzo disputes the statements of Defendants' Paragraph 48 as they relate to the accused PerkinElmer products as there is no admissible evidence cited in relation to these products; the McGall, Will, and Burczak Declarations address only the accused Affymetrix, Roche, and Amersham products, respectively. (Gunther Decl. Exs. 36, 32, 24 (McGall, Will, Burczak Decls.)).

Enzo disputes the statements of Defendants' Paragraph 48 to the extent that they characterize the accused products of Defendants' Exhibit 35 as utilizing "non-soluble signals." The accused products of Defendants' Exhibit 35 utilize soluble signals or their equivalents. (Perkins Decl. ¶¶ 26-29.) *See* Enzo's No. 46, 102-106.

Enzo disputes the statements of Defendants' Paragraph 48 to the extent that it characterizes the soluble signal of '373 claim 1 as not pinpointing the location of a hybridized sequence because it is uniformly dispersed. Fluorescence may be the "soluble signal" because the light photons are uniformly dispersed in solution and do not precipitate. *See* Enzo's No. 46. Thus, they can pinpoint the location of a hybridized sequence.

II. DISTRIBUTOR AGREEMENTS DO NOT BAR ENZO'S PATENT CLAIMS

A. Enzo's Agreement With Roche

DEFENDANTS' NO. 49

> Roche had a written agreement with Enzo entitled "Distribution and Supply Agreement" that took effect in 1994 and granted it rights to distribute and sell certain products notwithstanding Enzo patents. (Ex. 41, Enzo's First Amended Answer and Counterclaims ("ECC") ¶49.)

ENZO'S NO. 49

Undisputed that Roche and Enzo are current parties to an agreement entitled "Distribution and Supply Agreement" that took effect in 1994 and granted it **certain** rights to distribute and sell **certain** products notwithstanding Enzo patents. However, Enzo disputes that Enzo granted Roche **all** rights under its patents, or sufficient rights to avoid claims of infringement in this case.

REDACTED

REDACTED

DEFENDANTS' NO. 50

Roche was authorized by the 1994 distribution agreement with Enzo to distribute and sell to the research market certain "PRODUCTS" - i.e., products "covered by" certain Enzo patents. (Ex. 41, Enzo's First Amended Answer and Counterclaims ("ECC") 49; *see also* Ex. 40, Distribution Agreement at 1, App. A.)

ENZO'S NO. 50

Enzo does not dispute that Roche was authorized to distribute PRODUCTS to the research market only. (Roche Agreement § II.) Enzo disputes that Roche's sales were so limited. *See* Enzo's No. 51.

REDACTED

DEFENDANTS' NO. 51

Roche distributed and sold products as it was authorized. (Ex. 42, Declaration of Horst Togonal ("Togonal Decl.") ¶4-6.)

ENZO'S NO. 51

Disputed. Togonal Decl. ¶¶ 4-6 does not support the statement in Defendants' No. 51.

REDACTED

REDACTED

DEFENDANTS' NO. 52

Roche continuously made payments to Enzo under the distribution agreement on 13 of the products accused of infringing. (Ex. 42, Togonal Decl. ¶ 4.)

ENZO'S NO. 52

Disputed. REDACTED

REDACTED In any event, by Roche's admission, the amounts paid under the Agreement are "irrelevant" to the question of whether Roche is liable for patent infringement. *See* Renewed Motion at 37 (citing *Tessera, Inc. v. Int'l Trade Comm'n*, 646 F.3d 1357, 1370 (Fed. Cir. 2011).

REDACTED

DEFENDANTS' NO. 53

Roche's payments to Enzo under the distribution agreement began in 1994, or, in the case of new products, when they were first sold. (Ex. 42, Togonal Decl. ¶4.)

ENZO'S NO. 53

Disputed, for the reasons set forth in Enzo's No. 52.

DEFENDANTS' NO. 54

Roche has paid Enzo more than $23 million under the agreement. (Ex. 42, Togonal Decl. ¶4.)

ENZO'S NO. 54

Disputed, for the reasons set forth in Enzo's No. 52.

DEFENDANTS' NO. 55

Roche detailed its sales of these 13 products (among others) in quarterly written reports to Enzo. (Ex. 42, Togonal Decl. ¶5-7.)

ENZO'S NO. 55

Disputed, for the reasons set forth in Enzo's No. 52.

DEFENDANTS' NO. 56

The 14 products listed in ECC 54(3) are not among those Enzo accuses Roche of selling for unauthorized purposes.

ENZO'S NO. 56

Disputed. There is no citation to any evidence to support this statement.

B. Enzo's Agreement with PE

DEFENDANTS' NO. 57

PE had a written agreement with Enzo entitled "Distributorship Agreement." that took effect in 1999 and granted it rights to distribute and sell certain products, identified in Exhibit C of the Distributorship Agreement, notwithstanding Enzo patents. (Ex. 44, LeBlanc Decl., Ex. 1.)

ENZO'S NO. 57

Undisputed that PE and Enzo are parties to an agreement entitled "Distributorship Agreement" that took effect in 1999 and granted it **certain** rights to distribute and sell **certain** products notwithstanding Enzo patents. However, Enzo disputes that Enzo granted PE **all** rights under its patents, or sufficient rights to avoid claims of infringement in this case.

REDACTED

DEFENDANTS' NO. 58

PE developed, manufactured and sold the products listed on Exhibit C and paid Enzo a "transfer payment" based on the amount of product sold. (Ex. 44, LeBlanc Decl. Ex. 1, ¶14.)

ENZO'S NO. 58

Disputed. This statement is based on the inadmissible declaration of Paul LeBlanc, which Enzo moves to strike on the following grounds. REDACTED

REDACTED

REDACTED

REDACTED As such, Mr. LeBlanc's declaration is inadmissible hearsay, not based on personal knowledge. *See In re Singer Co.*, CA No. 01-6839, 2002 U.S. Dist. LEXIS 8609, at *28-29 (S.D.N.Y. May 14, 2002) (holding that a declaration that sets forth the actions of a corporation and not the actions of the other employees from whom he received information for the declaration is not admissible evidence if not based on the personal knowledge of the declarant).

In any event, disputed that the amount paid to Enzo was an adequate "transfer payment" under the terms of the PE Agreement. (Ex. 73 at 6-7, 12-13; Ex. 74 at 9-10.)

To the extent that PE manufactured and sold the products listed on Exhibit C to the PE Agreement, and that PE paid Enzo based on the amount of product sold, none of these statements are material. By PE's admission, the amounts paid under the Agreement are "irrelevant" to the question of whether Roche is liable for patent infringement. *See* Renewed Motion at 37 (citing *Tessera, Inc. v. Int'l Trade Comm'n*, 646 F.3d 1357, 1370 (Fed. Cir. 2011). Rather, the pertinent question is whether the terms of the PE Agreement authorize PE's specific activities. Defendants' No. 58 does not refer to the terms of the PE Agreement. To the contrary, PE exceeded the authority granted by the Agreement to manufacture and sell PRODUCTS in only limited circumstances. *See* Enzo's No. 51.

DEFENDANTS' NO. 59

> PE terminated the agreement at the end of 2004. (Ex. 44, LeBlanc Decl. ¶¶19, 20,21; Ex. 25, Mayer Decl. ¶36.)

ENZO'S NO. 59

Disputed that the PE Agreement was properly terminated. REDACTED

REDACTED

DEFENDANTS' NO. 60

The Ward patents expired at the end of 2004. (Ex. 6, '767 patent, Ex. 5, '824 patent.)

ENZO'S NO. 60

Undisputed.

DEFENDANTS' NO. 61

After terminating the agreement, PE ceased selling the Exhibit C products that are accused of infringing the '060 patent. (Ex. 25, Mayer Decl. ¶¶35, 36.)

ENZO'S NO. 61

Disputed that the PE Agreement was properly terminated. *See* Enzo's No. 59.

To the extent PE ceased selling products accused of infringing the '060 patent, this statement is immaterial to a determination of infringement, because PE was liable for exceeding the scope of its authority in the manufacture and unauthorized sale of infringing products prior to ceasing the sale thereof. *See* Enzo's No. 51.

DEFENDANTS' NO. 62

Excepting its AcycloPrime and Micromax products, the PE products accused of infringement are all products for which PE has paid, and Enzo has accepted, more than $15 million. (Ex. 44, LeBlanc Decl., ¶12.)

ENZO'S NO. 62

Disputed. By PE's admission, the amounts paid under the Agreement are "irrelevant" to the question of whether Roche is liable for patent infringement. *See* Renewed Motion at 37 (citing *Tessera, Inc. v. Int'l Trade Comm'n*, 646 F.3d 1357, 1370 (Fed. Cir. 2011). Rather, the pertinent question is whether the terms of the PE Agreement authorize PE's specific activities. Defendants' No. 58 does not refer to the terms of the PE Agreement. To the contrary, PE exceeded the authority granted by the Agreement to manufacture and sell PRODUCTS in only limited circumstances. *See* Enzo's No. 51.

DEFENDANTS' NO. 63

> PE labeled the products it sold as required by the agreement. (Ex. 44, LeBlanc Decl. ¶5.)

ENZO'S NO. 63

Disputed as not based on admissible evidence. *See* Enzo's No. 58. In any event, this statement is immaterial, because Enzo's claims of patent infringement do not depend on the exact form of the label used. PE infringed because it exceeded the authority granted by the Agreement to manufacture and sell PRODUCTS in only limited circumstances. *See* Enzo's No. 51.

III. GENUINE ISSUES OF MATERIAL FACT PRECLUDE SUMMARY JUDGMENT ON ENZO'S LANHAM ACT CLAIMS

DEFENDANTS' NO. 64

> The gravamen of Enzo's Lanham Act claim against the defendants is that defendants were marketing "products utilizing Enzo technology covered under issued patents which is not being attributed to Enzo". (Ex. 45, Weiner Tr. at 39.)

ENZO'S NO. 65

Disputed. This is not a material fact, but an incorrect legal contention. Defendants have violated the Court's August 25, 2011 order limiting the scope of the instant renewed motion to

"patent issues only" (*see* Docket No. 247) and reserve the right to respond at the appropriate time.

DEFENDANTS' NO. 66

> Enzo's claim is thus premised on a failure to list Enzo's patents on defendants' marketing materials.

ENZO'S NO. 67

Disputed. This is not a material fact, but an incorrect legal contention. Defendants have violated the Court's August 25, 2011 order limiting the scope of the instant renewed motion to "patent issues only" (*see* Docket No. 247) and reserve the right to respond at the appropriate time.

IV. ENZO'S ADDITIONAL MATERIAL FACTS OMITTED BY DEFENDANTS THAT PRECLUDE SUMMARY JUDGMENT

ENZO'S NO. 68

Defendants failed to move for summary judgment of non-infringement on approximately one hundred products accused of infringing the following patents in March 2005: (a) claim 1 of the '440 patent; (b) claims 1 and 5 of the '955 patent; (c) claims 1-3 of the '060 patent; (d) claim 42 of the '767 patent; and (e) claim 1 of the '824 patent. (*Compare* Exs. 1-2 *with* Gunther Decl. Exs. 23, 28, 34, 35.)

ENZO'S NO. 69

Exhibit 1 is a list of PerkinElmer and Roche products that infringe: (a) claims 1-3 of the '060 patent; (b) claim 1 of the '440 patent; and (c) claims 1 and 5 of the '955 patent. (*See* Exs. 14A-H to Sinden Decl.; Sinden Decl. ¶¶ 83-84)

ENZO'S NO. 70

The products listed on Exhibit 1 were each identified by Enzo in its March 2005 interrogatory responses. (Exs. 25-30.)

ENZO'S NO. 71

Defendants have not moved for summary judgment of non-infringement on the products and patent claims listed on Exhibit 1. (*Compare* Ex. 1 *with* Gunther Decl. Exs. 23, 28, 34, 35.)

ENZO'S NO. 72

Attached as Exhibits 14A-H to Dr. Sinden's declaration are unopposed claim charts demonstrating that the products identified on Exhibit 1 literally infringe (a) claims 1-3 of the '060 patent; (b) claim 1 of the '440 patent; and (c) claims 1 and 5 of the '955 patent by meeting each limitation of the asserted claims. (*See* Exs. 14A-H to Sinden Decl.; Sinden Decl. ¶¶ 83-84)

ENZO'S NO. 73

Exhibit 2 is a list of accused products that infringe: (a) claim 42 of the '767 patent; and (b) claim 1 of the '824 patent. (*See* Exs. 10-13 to Sinden Decl.; Sinden Decl. at ¶¶ 52, 72.)

ENZO'S NO. 74

The products listed on Exhibit 2 were each identified in Enzo's March 2005 amended interrogatory responses. (Exs. 25-30.)

ENZO'S NO. 75

Defendants failed to move for summary judgment of non-infringement on the products and patent claims listed on Exhibit 2. (*Compare* Ex. 2 *with* Gunther Decl. Exs. 23, 28, 34, 35.)

ENZO'S NO. 76

Attached as Exhibits 10-13 to Dr. Sinden's declaration are unopposed claim charts demonstrating that the products identified on Exhibit 2 literally infringe the asserted claims by meeting each and every limitation. (*See* Exs. 10-13 to Sinden Decl.; Sinden Decl. at ¶¶ 52, 72.)

ENZO'S NO. 77

Defendants marked many of their products with Enzo's patents, including the '824, '767, and '373 patents. (*See, e.g.*, Ex. 41.)

ENZO'S NO. 78

The Acyclonucleotide products are incorporated into and made an integral part of an "oligonucleotide" sequence, which includes both multiple nucleotides and pentose sugars. (Gunther Decl. Ex. 25, Mayer Decl., Ex. 1 at PE053621, Section IV; Sinden Decl. ¶ 63.)

ENZO'S NO. 79

There is an insubstantial difference between the acyclosugar moiety of the accused products of Gunther Decl. Ex. 28 and the disputed claim limitation. (Sinden Decl. ¶ 64.)

ENZO'S NO. 80

The acyclo products include an "acyclosugar moiety" which differs from pentose sugars in that a pentose sugar is cyclic or closed, and the other is an acyclic or an open sugar. (Sinden Decl. ¶ 64.)

ENZO'S NO. 81

The open-ringed structure of a nucleotide similar to Defendants' accused products in Gunther Decl. Ex. 28 is a sugar molecule which has been oxidized first. (Ex. 34, Bauman Tr. 108:2-117:14; Ex. 35 at AM78955.)

ENZO'S NO. 82

It was well known by persons of skill in the art at the time of infringement that an acyclosugar moiety as found in the accused products of Gunther Decl. Ex. 28 would be interchangeable with a pentose sugar as a design choice. (Sinden Decl. ¶ 65 and Ex. 18 thereto.)

ENZO'S NO. 83

REDACTED

ENZO'S NO. 84

REDACTED

ENZO'S NO. 85

The function of the disputed claim limitation in the asserted claims of the '767 and '824 patents, as well as the acyclic moiety in the accused products of Gunther Decl. Ex. 28, is to facilitate the incorporation of another nucleic base (that is labeled) into an oligonucleotide sequence so that the extended sequence can hybridize with its complementary sequence and be detected. (Sinden Decl. ¶ 64.)

ENZO'S NO. 86

The way that both the disputed claim limitation in the asserted claims of the '767 and '824 patents and the acyclic sugar moiety in the accused products of Gunther Decl. Ex. 28 accomplish their common function is to is through an enzymatic polymerase process whereby the sugar moiety of the base to be incorporated bonds with the 3' end group of the last base at the end of the sequence to be extended/labeled. (Sinden Decl. ¶ 64.)

ENZO'S NO. 87

The result in both the disputed claim limitation in the asserted claims of the '767 and '824 patents and the acyclic moiety in the accused products of Gunther Decl. Ex. 28 is that an additional base is incorporated onto the end of the DNA chain via the respective sugar molecules and the oligonucleotide sequence is "extend[ed] by the base" (Sinden Decl. ¶ 64; Gunther Decl. Ex. 25, Mayer Decl., Ex. 1, at PE053621.)

ENZO'S NO. 88

PerkinElmer marked its accused products of Gunther Decl. Ex. 28 with, *inter alia*, U.S. Patent No. 5,047,519 (the "'519 patent"). (Ex. 13.)

ENZO'S NO. 89

The '519 patent refers to the acyclic molecule of the accused products of Gunther Decl Ex. 28 as a "sugar" or "sugar portion" that persons that persons of skill in the art knew could be used to incorporate a base into a DNA sequence. (Ex. 13, '519 patent, at col. 9, line 25 – col. 10, line 28; Sinden Decl. ¶ 66.)

ENZO'S NO. 90

REDACTED

ENZO'S NO. 91

REDACTED

ENZO'S NO. 92

REDACTED

ENZO'S NO. 93

PE marked its dideoxynucleotide products with Enzo's patents and provided notice to Amersham of the same. (Ex. 41, at PE081146-49; Ex. 42.)

ENZO'S NO. 94

The function of the disputed limitation in the asserted '373 claims, as well as the complementary nucleic acid sequences of Defendants' accused products in Gunther Decl. Ex. 35, is to detect the presence and/or quantity of a polynucleotide sequence via hybridization with its complementary polynucleotide sequence. (Perkins Decl. ¶ 50).

ENZO'S NO. 95

The way in which disputed limitation in the asserted '373 claims, as well as complementary nucleic acid sequences of Defendants' accused products in Gunther Decl. Ex. 35, achieve the function noted in Paragraph 93 is by hybridizing the unlabeled polynucleotide sequence that is secured to a solid support with its unfixed free-floating complementary sequence that is labeled. (Perkins Decl. ¶ 50).

ENZO'S NO. 96

The result achieved by the the disputed limitation in the asserted '373 claims, as well as the complementary nucleic acid sequences of Defendants' accused products in Gunther Decl. Ex. 35, is detection and/or quantitation of a polynucleotide sequence of interest. (Perkins Decl. ¶ 50).

ENZO'S NO. 97

In both claim 1 of the '373 patent and in Defendants' accused products, the signal-generating moiety is different from the soluble signal itself. (Perkins Decl. ¶ 28.)

ENZO'S NO. 98

The soluble signal of the '373 patent and Defendants' accused products may be light or some other quantifiable signal. (Perkins Decl. ¶ 28).

ENZO'S NO. 99

The function of the disputed limitation of the '373 patent, as well as the signals of Defendants' accused products in Gunther Decl. Ex. 35, is to enable the detection and/or quantitation of the presence of a targeted polynucleotide sequence. (Perkins Decl. ¶ 30.)

ENZO'S NO. 100

The way that the disputed limitation of the '373 patent, as well as the signals of Defendants' accused products in Gunther Decl. Ex. 35, perform the function of Enzo's No. 104 above is through the use of at least one detectable signal such as fluorescence, color, or enzyme that does not precipitate. (Perkins Decl. ¶ 30.)

ENZO'S NO. 101

The result achieved by the disputed limitation of the '373 patent, as well as the signals of Defendants' accused products in Gunther Decl. Ex. 35, is the detection and quantitation of a polynucleotide sequence of interest. (Perkins Decl. ¶ 30.)

ENZO'S NO. 102

When the accused Amersham products and accused PerkinElmer labeling kits in Gunther Decl. Ex. 35 are used as intended or directed, the end-user of these products will generate a polynucleotide sequence that is labeled that will be used to hybridize and attach to a solid support and generate a detectable signal in a manner that infringes claim 1 of the '373 patent. (Perkins Decl. ¶¶ 33, 51.)

ENZO'S NO. 103

Amersham's intended use for its accused products is demonstrated by the "suggested microarray hybridization protocol" in the instruction manual for the accused products. (Perkins Decl. ¶ 33, 51.)

ENZO'S NO. 104

The accused PerkinElmer MicroMax products do not result in the detection of an insoluble precipitate or depend on whether the slide is wet or dry. (Perkins Decl. ¶ 34.)

ENZO'S NO. 105

Detection of the signal in the accused MicroMax products is not dependent on any precipitate; a precipitate is something that cannot be dissolved. (Perkins Decl. ¶ 35.)

ENZO'S NO. 106

Defendants' authority to sell products to the research market for research purposes only did not extend to the sale for "commercial purposes," including commercial product development by a commercial entity. (Ex. 46, Englehardt Dep. 380:11-16; Ex. 47, Hendrickson Dep. 41:14-16; Ex. 48, at 322957-58; Ex. 8, § 1.e.; Ex. 9, § XV; Ex. 49.)

ENZO'S NO. 107

REDACTED

ENZO'S NO. 108

PerkinElmer sold or shipped PRODUCTS to commercial entities, including, but not limited to, REDACTED

REDACTED

ENZO'S NO. 109

REDACTED

ENZO'S NO. 110

REDACTED

ENZO'S NO. 111

Orchid contracted with NEN/PerkinElmer to provide PRODUCTS as reagents for its SNPstream systems which, in turn, were sold to, *inter alia*, large commercial entities such as SmithKline Beecham and Monsanto. (Ex. 9 at 15; Ex. 60 at 13 and 17 and Exs. 61-63.)

ENZO'S NO. 112

Roche sold products to Oncor, a commercial entity, notwithstanding Enzo's admonitions to refrain from selling or using Products for commercial purposes. (Ex. 64, Roach Dep. 40:17-41:1; Ex. 65; Ex. 66.)

ENZO'S NO. 113

REDACTED

REDACTED

ENZO'S NO. 114

REDACTED

ENZO'S NO. 115

REDACTED

ENZO'S NO. 116

REDACTED

ENZO'S NO. 117

REDACTED

ENZO'S NO. 118

In *Enzo Biochem, Inc. v. Applera Corp.* No. 04-929, 2006 WL 2927500 (D. Conn. Oct. 12, 2006) (the "Connecticut Action"), Judge Arterton construed the "A" limitation of the '824 and '767 patents to mean that "A comprises at least three carbon atoms and is one or more parts of a signalling moiety, which includes, in some instances, the whole signalling moiety." (Ex. 19, at *4.)

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